WE CLAIM:

1. A controlled release nanoparticulate composition comprising:

(a) a poorly soluble agent to be administered having an effective average particle size of less than about 1000 nm;

(b) at least one surface stabilizer associated with the surface of the agent, and

(c) at least one pharmaceutically acceptable rate-controlling polymer,

wherein the composition provides controlled release of the agent for a time period ranging from about 2 to about 24 hours or longer.

2. The composition of claim 1, wherein the effective average particle size of the agent is selected from the group consisting of less than about 800 nm, less than about 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

3. The composition of claim 1, wherein the concentration of the polymer is from about 5 to about 95% (w/w).

4. The composition of claim 3, wherein the concentration of the polymer is from about 10 to about 65% (w/w).

5. The composition of claim 1 additionally comprising a binder agent in an amount of from about 0.1 to about 10% (w/w).

6. The composition of claim 1 additionally comprising a lubricant in an amount of from about 0.1 to about 10% (w/w).

7. The composition of claim 6, wherein the lubricant is selected from the

group consisting of magnesium stearate, hydrogenated vegetable oil, and stearic acid.

8. The composition of claim 1, wherein the solid dose formulation is made by wet granulation.

9. The composition of claim 1 formed by wet granulation, wherein water is added to the agent, surface stabilizer, and polymer to form granules prior to forming the solid dose of the controlled release formulation.

10. The composition of claim 1, wherein the rate-controlling polymer is selected from the group consisting of gum arabic, agar, guar gum, cereal gums, dextran, casein, gelatin, pectin, carrageenan, waxes, shellac, hydrogenated vegetable oils, polyvinylpyrrolidone, hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HEC), hydroxypropyl methylcelluose (HPMC), sodium carboxymethylcellulose (CMC), poly(ethylene) oxide, alkyl cellulose, ethyl cellulose, methyl cellulose, carboxymethyl cellulose, hydrophilic cellulose derivatives, polyethylene glycol, polyvinylpyrrolidone, cellulose acetate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl acetate phthalate, hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate, polyvinyl acetaldiethylamino acetate, poly(alkylmethacrylate), poly(vinyl acetate), polymers derived from acrylic or methacrylic acid and their respective esters, and copolymers derived from acrylic or methacrylic acid and their respective esters.

11. The composition of claim 10, wherein the rate-controlling polymer is HPMC.

12. The composition of claim 10, wherein the rate-controlling polymer is a polymer derived from acrylic or methacrylic acid and their respective esters or copolymers

derived from acrylic or methacrylic acid and their respective esters.

13. The composition of claim 1, wherein the poorly water soluble agent is present in an amount of from about 1 μg to about 800 mg.

14. A dosage form comprising a controlled release nanoparticulate composition according to claim 1 , wherein the dosage form is in tablet form or in multiparticulate form.

15. The dosage form of claim 14, wherein the agent and at least one auxilary excipient are compressed into tablet form prior to coating with a rate controlling polymer.

16. The dosage form of claim 14, wherein the agent, the rate controlling polymer and at least one auxilary excipient are compressed to form a controlled release matrix tablet.

17. The dosage form of claim 16, wherein the controlled release matrix is coated with a rate controlling polymer.

18. The dosage form of claim 14, wherein the agent and at least one auxilary excipient are compressed into the form of a multilayer tablet prior to coating with a rate controlling polymer.

19. The dosage form of claim 14, wherein the agent is dispersed in the rate controlling polymer material and compressed into the form of a multilayer tablet.

20. The dosage form of claim 19, wherein the multilayer tablet is coated with a rate controlling polymer.

21. The dosage form according to claim 14, wherein the agent, at least one auxiliary excipient, and the rate controlling polymer material are combined into a multiparticulate form.

22. The dosage form according to claim 21, wherein the multiparticulate form comprises discrete particles, pellets, minitablets, or combinations thereof.

23. The dosage form according to claim 21, wherein the multiparticulate is encapsulated in hard or soft gelatin capsules.

24. The dosage form according to claim 21 wherein the multiparticulate is incorporated into a sachet.

25. The dosage form according to claim 22 wherein the discrete particles or pellets are compressed into tablet form.

26. The dosage form according to claim 25 wherein the tablet form is coated with a rate controlling polymer material.

27. The dosage form according to claim 22 wherein the discrete particles or pellets are compressed into a multilayer tablet.

28. The dosage form according to claim 27 wherein the multilayer tablet is coated with a rate controlling material.

29. The dosage form according to claim 14 wherein the tablet further comprises an osmagent added to the controlled release composition to form an admixture and a semi-

permeable membrane; the semi-permeable membrane surrounding the admixture and being permeable to aqueous media, but impermeable to the poorly soluble drug compound or pharmaceutically acceptable salt thereof and the semi-permeable membrane defining an orifice therein.

30. A method of preparing a solid dose controlled release nanoparticulate formulation comprising:

(a) combining a nanoparticulate composition of an agent to be administered and at least one surface stabilizer associated with the surface of the agent, wherein the composition has an effective average particle size of less than about 1000 nm and at least one suitable rate-controlling polymer; and

(b) forming a solid dose of the mixture from step (a), wherein the solid dose formulation has a controlled release of the agent following administration for a time period ranging from about 2 to about 24 hours or longer.

31. The method of claim 30, wherein the effective average particle size of the agent particles is selected from the group consisting of less than about 800 nm, less than about 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

32. The method of claim 30, wherein the concentration of the polymer is from about 5 to about 95% (w/w).

33. The method of claim 32, wherein the concentration of the polymer is from about 10 to about 65% (w/w).

34. The method of claim 31, comprising adding water to the nanoparticulate agent, surface stabilizer, and rate-controlling polymer to form granules prior to step (b).

35. A method of treating a mammal comprising administering to the mammal an effective amount of a solid dose controlled release nanoparticulate formulation wherein:

(a) the formulation comprises nanoparticulate agent particles to be administered and at least one surface stabilizer associated with the surface of the nanoparticulate agent, wherein the agent particles have an effective average particle size of less than about 1000 nm and at least one suitable rate-controlling polymer; and

(b) the formulation has a controlled release of the agent following administration for a time period ranging from about 2 to about 24 hours or longer.

add C'

add D'